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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CL04PT	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/IT2005/000060	International filing date *(day/month/year)* 10.02.2005	Priority date *(day/month/year)* 18.02.2004
International Patent Classification (IPC) or national classification and IPC INV. A41D13/11 A62B23/02 A62B18/10 A62B18/08		
Applicant CL.COM S.R.L. et Al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.08.2005	30.05.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Triantaphillou, P Telephone No. +31 70 340-2785

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IT2005/000060

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15	as originally filed

Claims, Numbers

1-21	received on 16.08.2005 with letter of 10.08.2005

Drawings, Sheets

1/5-5/5	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-4 536 440 (BERG ET AL) 20 August 1985 (1985-08-20)

1.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows:

"A mask for the protection against biological agents consisting in a plurality of layers, at least one of them, having filtering functions."

The subject-matter of claim 1 differs from this known mask in that:

"at least one of the[m layers], having filtering functions, is composed of borosilicate micro-glass fibres bound together by a vinyl acetate resin, the fibre matrix being supported by a strong, cellulose based, substrate and the structure being treated with a silicone based coating to impart hydrophobic properties."

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

1.2 The problem to be solved by the present invention may be regarded as *improve filtering properties against biological agents and improve the efficiency.*

1.3 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
In the present application differs from the prior art masks in the selections for each layer and the consequent technical effects this has.
Furthermore, the solution to the objective problem has neither been disclosed nor suggested in the prior art.

1.4 Claims 2-21 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VIII

Certain observations on the international application

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

REPLACEMENT SHEETS

CLAIMS

1. A mask for the protection against biological agents consisting in a plurality of layers, characterized in that at least one of them, having filtering functions, is composed of borosilicate micro-glass fibers bound together by a vinyl acetate resin, the fiber matrix being supported by a strong, cellulose based, substrate and the structure being treated with a silicone based coating to impart hydrophobic properties.
2. A mask as claimed in claim 1 composed of three layers of material:
   - a central layer, having filtering function, composed of borosilicate micro-glass fibers bound together by a vinyl acetate resin, the fiber matrix being supported by a strong, cellulose based, substrate and the structure being treated with a silicone based coating to impart hydrophobic properties

- an inner layer having shape-retaining function
- an outer layer having covering function

3. A mask as claimed in claim 2 characterized in that the filter layer has thickness ranging between 150 and 400 microns and unit area ranging between 25 and 65 g/m^2.
4. A mask as claimed in claim 2 characterized in that the inner layer, with the function of retaining shape and providing structure to the mask body as well as providing support for the filtration layer, is made from non-woven fabric obtained by polypropylene or polyester fibers
5. A mask as claimed in claim 2 characterized in that the inner layer is made from non-woven fabric consisting in polypropylene fibers

6. A mask as claimed in claim 2 characterized in that the outer layer, having covering function to protect the filtration layer from abrasion, is made from non-woven fabric obtained by polyolefins, polyester or nylon fibers
7. A mask as claimed in claim 2 characterized in that the outer layer is made from meltblown polypropylene fibers
8. A mask as claimed in claim 1, equipped with a valve to facilitate the breathing which opens, in response to increased pressure, when the wearer exhales, allowing air to be rapidly evacuated from the mask interior, and which closes during inhaling
9. A mask as claimed in claim 8, characterized in that the valve comprises a valve seat (a) over which is secured a raised valve cover (b), carrying apertures (c).

   The seat is composed by a flat surface (d), having orifices (e) which allow the air flow.

   In the centre of the seat, a low thickness relief (f) rises.

   The cover is equipped with apertures (c), allowing the air passing through. Inside the cover, in the centre, a valve flap (h) is attached by an appropriate support (g); the flap is made from flexible material and represents the mobile component which opens and closes the valve. The valve can be made from the various materials suitable for thermoforming, preferably is made from moulded polypropylene; the flap is made from an elastic flexible material such as, for example, synthetic rubber.

   The valve is attached to the centre of the mask where an aperture is also created.

When the wearer inhales, the valve flap seals against the relief, preventing air from flowing, while, when the wearer exhales, the valve flap lift away from the relief, letting air pass through.

Consequently, inhaled air enters the mask exclusively through the filter media of the mask whereas exhaled air passes through the aperture of the mask and the orifices in the valve.

10. A mask as claimed in claim 9 characterized in that the relief (f) of the valve seat owns a concave surface wherein a continuos, cylinder shaped, plastic (i) lays all along the surface of the relief.

The plastic can be made from synthetic polymers obtained from different monomers and can be produced with different mixtures, for example, with fluoro, silicone or nitrile based mixtures.

The plastic is designed, in terms of dimensions and structure, to provide the highest seal during closing. In fact, when the valve flap seals against the relief, it goes into direct contact with the plastic; then, due to the dimensions of the flap support and the plastic thickness, the valve flap flexes up on the edges.

The flap material, thanks to its intrinsic memory and to elastic properties, perfectly seals onto the plastic surface; in addition, the compatibility of the two materials, having the same chemical-physical superficial properties, ensures a perfect adherence.

11. A mask as claimed in claim 10 characterized in that the relief of the valve seat is circular, the valve flap is round shaped and the continuos, cylinder shaped, plastic is an O-ring which lays all over the circumference of the relief.

12. A mask as claimed in claim 11 characterized in that the valve's components have shapes and dimensions as shown in fig. 13.

13a: valve seat, front view

x: 45 mm

y: 30 mm

z: 26 mm

13b: valve seat, side view

x: 1mm

y: 4.2 mm

z: 4 mm

13c: valve cover, front view

x: 32 mm

y: 30 mm

z: 18 mm

13d. valve cover, side view

x: 8 mm

y: 3 mm

z: 1 mm

w: 3.5 mm

13e: valve flap

x (diameter): 30 mm

13. A mask as claimed in claim 1 characterized in that the mask is equipped, on the edges, with a boundary sealing layer to improve the seal; the boundary layer is applied all along the perimeter of the mask, starting

from the side joins; the seal layer tightly fits over the wearer's face adapting to any face shape; that ensures a leak free contact to the wearer's face, without pin holes and distorsions which would allow contaminants to pass through the mask body without being removed by the filtering material.

14. A mask as claimed in claim 13 characterized in that the material of the boundary sealing layer is made from a natural rubber latex resin or a silicone based resin

15. A mask as claimed in claim 13, characterized in that the boundary sealing layer is made from natural rubber latex applied in some 2 mm thickness and in unit area ranging between 200 and 400 g/m^2

16. A mask as claimed in claim 1, characterized in that, adjoining the boundary sealing layer as claimed in claim 13, a strip, made from the same material than the boundary sealing layer, is applied in the nose clip area; the strip makes the mask more comfortable to wear and, further on, improves the seal between the mask and the face at the nose portion wherein deformations and plies may normally be present

17. Use of the mask as claimed in any of claims 1 or 10 as protective mean against biological agents

18. Use of the mask as claimed in any of claims 1 or 10 and comprising a boundary sealing layer as claimed in claim 13, as protective mean against biological agents

19. Use of the masks as claimed in claim 1 as protective mean against Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Human Immunodeficiency Viruses (HIV), Sp. Pseudomonas, Staphylococcus aureus, Serratia Marcescescens, Bacillus Anthracis

20. A valve as claimed in any of claims 10 or 11 to facilitate the breathing of a mask as claimed in claim 1

21. A boundary sealing layer as claimed in any of claims 13 to 15 to improve the hermetic seal of a mask as claimed on claim 1